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Attorneys for Defendant
ABBOTT LABORATORIES

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STEPHEN WENDELL AND LISA WENDELL, for themselves and as successors in interest to MAXX WENDELL, DECEASED,

Plaintiffs,

v.

JOHNSON & JOHNSON; CENTOCOR, INC.; ABBOTT LABORATORIES; SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICALS USA; GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA; PAR PHARMACEUTICAL, INC.;

Defendants.

Case No: 4:09-cv-04124-CW

DEFENDANT ABBOTT LABORATORIES' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

Date: August 11, 2011
Time: 2:00 p.m.
Courtroom: Room 2, 4th Floor
1301 Clay Street
Oakland, CA 94612

Judge: Honorable Claudia Wilken

DEFENDANT ABBOTT LABORATORIES' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on Thursday, August 11, 2011, at 2:00 p.m., in Courtroom No. 2 of the United States District Court for the Northern District of California, 1301 Clay Street, Oakland, California, 94612, Honorable Claudia Wilken presiding, Defendant ABBOTT LABORATORIES ("Abbott") will and hereby does move this Court for summary judgment under Federal Rule of Civil Procedure 56.

Abbott respectfully moves for summary judgment pursuant to Rule 56 on all claims for relief asserted by plaintiffs STEPHEN WENDELL and LISA WENDELL, his wife, for themselves and as successors-in-interest to MAXX WENDELL ("Mr. Wendell"), deceased (collectively, "Plaintiffs") against Abbott, on the ground that there is no genuine issue as to any material fact related to the two causes of action against Abbott—the First and Second Counts of the Fourth Amended Complaint—both of which are based on a theory of failure to warn. Abbott is entitled to judgment as a matter of law because the treating physician prescribed Mr. Wendell Humira with knowledge of the specific risk Plaintiffs allege was associated with Humira. Plaintiffs therefore cannot establish a necessary element of their failure-to-warn causes of action—that the allegedly inadequate warning caused their injuries.

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MEMORANDUM OF POINTS AND AUTHORITIES

I. PRELIMINARY STATEMENT

The undisputed material facts in this case establish as a matter of law that the alleged failure to warn on which Plaintiffs' claims against Abbott Laboratories ("Abbott") are based was not the proximate cause of Plaintiffs' alleged injuries. Abbott's motion for summary judgment of Plaintiffs' strict liability and negligence claims therefore should be granted. Both claims are predicated on an alleged failure to warn of the risk of hepatosplenic T-cell lymphoma ("HSTCL") in pediatric patients associated with using Humira. The testimony of the treating physician in this case, Dr. Edward Rich, unequivocally establishes, however, that he was aware of the ***precise risk*** Plaintiffs describe in their Fourth Amended Complaint ("FAC") when he prescribed Humira. In light of this testimony, Plaintiffs cannot establish that a different warning would have changed Dr. Rich's decision to prescribe Humira. Accordingly, Plaintiffs cannot prove causation, an essential element of both of their claims against Abbott, and both claims fail as a matter of law.

Under California's learned intermediary doctrine, the only relevant inquiry on the point of causation with respect to Abbott is whether a different warning would have changed Dr. Rich's decision to prescribe Humira. Plaintiffs' case against Abbott fails because Dr. Rich's testimony affirmatively establishes that the warning Plaintiffs urge was required would have had no impact on his decision. In his April 11, 2011 deposition, Dr. Rich testified that TNF inhibitors, a class of drugs which includes Humira and Remicade (two of the drugs prescribed to Maxx Wendell), are a very important part of the treatment of inflammatory bowel disease ("IBD"). Dr. Rich keeps himself apprised of the potential risks associated with this class of medications in many ways—by attending conferences and meetings of pediatric gastroenterologists, through discussions with gastroenterologist colleagues, and by reading case reports, reports of clinical studies of these drugs, and articles published in the field. He learned of the early cases of HSTCL in patients taking Remicade in combination with mercaptopurine and other immunosuppressants through his review of the literature. He testified repeatedly that as soon as he learned of these cases, he made it his practice to warn all of his patients for whom

he recommended any TNF inhibitor, including Humira, of this potential risk. And, crucially, Dr. Rich testified that he continued to prescribe these medications to his patients, including Maxx Wendell, after he became aware of the alleged risk associated with these therapies. Dr. Rich's testimony irrefutably establishes that the warning Plaintiffs argue was required would not have changed his decision to prescribe Humira to Maxx Wendell. For these reasons, Plaintiffs cannot establish the element of causation required to make out both their strict liability and negligence claims against Abbott. Accordingly, Abbott's motion for summary judgment should be granted.

II. STATEMENT OF FACTS

A. Dr. Rich's Treatment of Maxx Wendell

Maxx Wendell was first seen by Dr. Edward Rich, a pediatric gastroenterologist, in September 1998 at the age of twelve. Declaration of Traci L. Shafroth in Support of Defendant Abbott Laboratories' Motion for Summary Judgment ("Shafroth Decl.") ¶ 2, Ex. 1 (Transcript of Deposition of Dr. Edward J. Rich ("Rich Dep.") 38:6-18, 49:25-50:13). Dr. Rich diagnosed Mr. Wendell with probable ulcerative colitis, a type of inflammatory bowel disease. *Id*. at 59:19-23, 69:4-70:1, 74:3-75:1. Dr. Rich initially treated Mr. Wendell with Prednisone (a steroid) and Asacol (an aspirin anti-inflammatory) in an attempt to induce remission of Mr. Wendell's IBD. *Id*. at 72:13-72:23, 75:2-12, 82:3-8. Mr. Wendell continued to experience IBD flares on this regimen, so in July 1999 Dr. Rich added mercaptopurine (brand name Purinethol; also known as 6-mp or 6-mercaptopurine), an immunosuppressant, to Mr. Wendell's mediations. *Id*. at 78:16-82:2, 83:11-20, 85:1-86:22, 105:6-15. The purpose of prescribing mercaptopurine was to induce remission and allow Dr. Rich to wean Mr. Wendell off steroids.[1] *Id*. at 82:9-83:10. This treatment was also unsuccessful, however, as Mr. Wendell continued to experience IBD flares through early 2002. *Id*. at 109:23-110:21, 115:15-116:7. In May 2002, Dr. Rich began to

[1] Dr. Rich wanted to wean Mr. Wendell off steroids in part because of the serious side effects associated with chronic steroid use, including, among other things, osteoporosis and diabetes. Shafroth Decl. ¶ 2, Ex. 1 (Rich Dep. 86:13-87:10).

discuss TNF inhibitor therapy with Mr. Wendell as another treatment option. *Id*. at 117:4-118:1, 122:10-123:10.

In July 2002, Dr. Rich began to prescribe Mr. Wendell Remicade (infliximab), a TNF blocker, in hopes that initiation of this therapy would allow him to permanently wean Mr. Wendell off steroids. *Id*. 147:24-148:16, 151:14-152:8. Mr. Wendell's response to Remicade was immediate—at his next visit, two weeks later, Mr. Wendell reported no IBD symptoms. *Id*. at 153:22-154:16. Mr. Wendell took Remicade in combination with mercaptopurine from July 2002 to March 2006. *Id*. 147:24-148:16, 177:12-24. At a visit in November 2005, Dr. Rich discussed discontinuing Remicade with Mr. Wendell if his next colonoscopy was clear. *Id*. at 170:24-173:5. At this visit, Dr. Rich also discussed with Mr. Wendell the possibility of introducing Humira (adalimumab). *Id*. As he typically did with his high school and college-aged patients, Dr. Rich discussed switching from Remicade to Humira with Mr. Wendell, in part because Humira could be injected at home—unlike Remicade, which required a two- to three-hour infusion at Dr. Rich's clinic. *Id*. at 174:1-22.

Mr. Wendell was free from symptoms at his next colonoscopy, in May 2006, so Dr. Rich discontinued the use of Remicade (although he continued to prescribe mercaptopurine at this time). *Id*. at 198:1-199:7. Mr. Wendell experienced another IBD flare in November 2006, at which point Dr. Rich prescribed Humira. *Id*. at 200:2-19, 216:25-217:10. Mr. Wendell was diagnosed with HSTCL in July 2007. FAC ¶ 58.

B. Reports Are Made Public of Hepatosplenic T-cell Lymphoma in Patients Taking Remicade in Combination with Mercaptopurine

In May 2006, the FDA approved Remicade for an additional indication—the treatment of active pediatric Crohn's disease. FAC at ¶ 39. In addition to the changes to the Remicade label related to the new indication, the FDA required the inclusion of a black box warning to report six post-marketing cases of HSTCL in pediatric patients or young adults taking Remicade in conjunction with either mercaptopurine or azathioprine (another immunosuppressant). *Id*. at ¶ 40. The manufacturer of Remicade sent out a Dear Health Care Practitioner letter shortly after it

received FDA approval of the language, including the additional warning information based on the six post-marketing cases of HSTCL. Shafroth Decl. ¶ 2, Ex. 1 (Rich Dep. 200:22-202:22).

C. Dr. Rich Becomes Aware of the Risks Associated with TNF Inhibitors Taken Alone or in Combination with Mercaptopurine and Continues to Prescribe These Medications for Wendell Despite Those Risks

Dr. Rich testified that TNF inhibitors were an important part of his treatment of patients with inflammatory bowel disease. *Id*. at 205:11-25. He stayed abreast of evolving information about the risks associated with these drugs (1) by attending conferences and regional meetings of gastroenterologists, (2) through discussions with pediatric and adult gastroenterologist colleagues, and (3) by reading case reports, reports of clinical studies of these medications, and articles published in the field. *Id*. at 250:17-252:7, 191:24-192:10, 193:23-194:18, 124:24-126:3, 132:25-133:25. He would have received the May 2006 Dear Health Care Practitioner letter (*id*. at 200:22-202:22), but, through his monitoring of the literature in the field he was already aware of the post-marketing cases of HSTCL before he received the letter and before the black box warning regarding HSTCL was added to Remicade. *Id*. at 214:23-215:22, 200:22-202:22, 203:18-207:5.

As soon as he became aware of these reports, Dr. Rich began warning all of his patients taking TNF inhibitors, including Mr. Wendell, of the specific risk of HSTCL. *Id*. at 209:6-210:4, 214:23-215:22; 241:4-21. He continued to prescribe Mr. Wendell Remicade in combination with mercaptopurine in 2006 after he became aware of the reports relating to HSTCL. *Id*. at 214:23-215:22. He believed that the association between HSTCL and therapy with Remicade in combination with immunosuppressants such as mercaptopurine applied to the entire class of TNF inhibitors, including Humira. *Id*. at 137:21-138:5, 264:21-265:19. After discussing with Mr. Wendell "the specific increased risk of hepatosplenic T-cell lymphoma" (*id*. at 265:4-19; *see also id*. at 241:4-21), Dr. Rich reinitiated anti-TNF therapy after Mr. Wendell experienced an IBD flare in November 2006, prescribing Humira in combination with mercaptopurine. *Id*. at 227:10-228:12.

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III. ARGUMENT

A. Summary Judgment Standard

Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). If the moving party meets its initial burden of demonstrating the absence of a genuine issue of material fact, the burden shifts to the nonmoving party to establish, beyond the pleadings, that there is a genuine issue for trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). Summary judgment for a defendant is appropriate when the plaintiff "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Id*. at 322. Where a party who will bear the burden of proof at trial fails, after adequate time for discovery, to make a showing sufficient to establish the existence of an element essential to its case, "the plain language of Rule 56(c) mandates the entry of summary judgment." *Id*. "In such a situation, there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Id*. at 322-23 (citation omitted).

B. Plaintiffs' Claims Against Abbott Fail Because Plaintiffs Cannot Prove That Humira Was the Proximate Cause of Their Alleged Injuries.

The Court should grant summary judgment for Abbott because Dr. Rich prescribed Humira for Mr. Wendell knowing of the precise alleged risk Plaintiffs argue Abbott should have warned about. Plaintiffs therefore cannot show that Abbott's alleged failure to warn was the proximate cause of their injuries. California follows the learned intermediary doctrine, which specifies that in the case of prescription drugs, the duty to warn "runs to the physician, not to the patient." *Carlin v. Super. Ct.*, 13 Cal. 4th 1104, 1116 (1996) (citations omitted). Crucially, "a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician." *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (affirming grant of summary judgment for defendant on basis that manufacturer's alleged failure to provide adequate warnings did not cause patient's suicide); *see also Ramirez v. Plough, Inc.*, 6 Cal. 4th 539, 556 (1993) (holding,

under similar circumstances, that "there is no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury"). In particular, a plaintiff cannot prove that an allegedly inadequate warning was the proximate cause of his or her injury where the treating physician knew of the risk at issue as "no one needs notice of that which he already knows." *See, e.g.*, *Plummer v. Lederle Labs., Div. of Am. Cyanamid Co.*, 819 F.2d 349, 359 (2d Cir. 1987) (relied on by the Ninth Circuit in *Motus v. Pfizer Inc.* 358 F.3d 659 (9th Cir. 2004)) (citation omitted).

The burden of proof in this failure-to-warn case is on Plaintiffs, who must prove that the alleged failure to warn or inadequate warning was a "substantial factor" in bringing about Mr. Wendell's injuries. *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd sub nom. Motus v. Pfizer Inc.*, 358 F.3d 659 (9th Cir. 2004) (citing *Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 968 (1997)). In other words, Plaintiffs "must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus*, 196 F. Supp. 2d at 991.

The Ninth Circuit's decision in *Motus* demonstrates that Plaintiffs cannot meet their burden of showing that Abbott's alleged failure to warn was the legal cause of Mr. Wendell's injury. In *Motus*, the plaintiff's husband committed suicide shortly after being prescribed the antidepressant Zoloft. *Id*. The district court granted summary judgment for Pfizer, holding that the plaintiff had failed to create a genuine issue as to whether Pfizer's alleged failure to adequately warn of the risk of suicide associated with Zoloft caused her injuries because the prescribing physician testified that he did not rely on any statements or written materials from Pfizer in making his decision to prescribe Zoloft. *Id*. at 996, 999. The Ninth Circuit affirmed, finding that in light of this testimony, stronger warnings would not have altered the physician's conduct. *Motus*, 358 F.3d at 661 (finding "the adequacy of Pfizer's warnings . . . irrelevant to the disposition of this case.").

In evaluating the causation requirement in *Motus*, the Ninth Circuit relied on a Second Circuit case, *Plummer, supra*. *Motus*, 358 F.3d at 661. In *Plummer*, the treating physician testified that he knew of the risk of contact polio plaintiff argued defendant should have warned

about, but prescribed defendant's vaccine without warning the patient's mother of that risk. 819 F.2d at 358-59. The court held that on these facts, judgment notwithstanding the verdict should have been entered for the defendant because "a reasonable jury could not have found proximate cause." *Id*.; *see also Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 (1992) ("We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the . . . physician."); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) ("If the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of warning is not a producing cause of injury."); *Dunn v. Lederle Labs.*, 328 N.W.2d 576, 582 (Mich. Ct. App. 1982) (affirming jury verdict for defendant where doctor testified he was aware of the risk plaintiffs argued defendant should have warned of).

Here, as in *Motus* and *Plummer*, Plaintiffs cannot establish that a stronger warning would have altered the conduct of the prescribing physician and therefore cannot meet their burden of proving causation. Plaintiffs allege that "at no time during the times relevant to this action did defendant Abbott Laboratories advise prescribing physicians or the general public in the United States about the known or knowable risk of hepatosplenic T-cell lymphoma in pediatric patients using Humira concomitantly with immunomodulating drugs like 6-MP . . . ." FAC ¶ 65. But Dr. Rich's testimony firmly establishes that (1) he was apprised of the potential risks of TNF blockers from his own efforts and (2) that TNF blocking therapy was nonetheless medically indicated and Humira was prescribed for that reason. *See supra* Sections II.A., C. In short, even if the warning Plaintiffs argue was required had been provided, it would have had no impact on Dr. Rich's decision to prescribe Humira to Mr. Wendell.

Dr. Rich testified that he learned of the cases of HSTCL associated with patients taking Remicade in combination with mercaptopurine in 2005 when they were reported in the literature. Shafroth Decl. ¶ 2, Ex. 1 (Rich Dep. 214:23-215:22). As soon as he became aware of these reports, he began warning all of his patients taking any TNF inhibitors, including Mr. Wendell, of the specific potential risk of HSTCL. *Id*. at 214:23-215:22; 241:4-21. He continued prescribing Remicade in combination with mercaptopurine for Mr. Wendell in 2006 even after he learned of these reports. *Id*. at 214:23-215:22 In early 2006, he discontinued Mr. Wendell's

use of Remicade, but reinitiated anti-TNF therapy with Humira in November 2006 when Mr. Wendell again experienced an IBD flare. *Id*. at 215:15-22, 216:10-217:10. Dr. Rich testified that he concluded that the alleged association with HSTCL applied to all TNF inhibitors, including Humira (*id*. at 264:21-265:19) and that he discussed with Mr. Wendell "the specific increased risk of hepatosplenic T-cell lymphoma" before prescribing Humira. *Id*. at 265:4-19. Dr. Rich prescribed Humira in combination with mercaptopurine with knowledge of these alleged risks. *Id*. at 240:23-241:21. Dr. Rich's testimony incontrovertibly establishes that a stronger warning would not have changed his decision to prescribe Humira in combination with mercaptopurine to Mr. Wendell. Because "stronger warnings would not have altered the conduct of the prescribing physician[,]" Plaintiffs' "product defect claims based on insufficient warnings cannot survive summary judgment." *Motus*, 358 F.3d at 661; *see also Ferguson v. Proctor & Gamble Pharms., Inc.*, 353 F. Supp. 2d 674, 679 (E.D. La. 2004) (granting summary judgment based on the prescribing physician's representation that he would have prescribed the drug knowing of the risk of developing the condition of which plaintiff suffered). Further, as in *Plummer*, "no harm could have been caused by failure to warn of a risk already known." *Plummer*, 819 F.2d at 359 (citing *Rosburg v. Minn. Mining & Mfg. Co.,* 181 Cal. App. 3d 726, 730 (1986); *see also In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 06-CV-2782, 2009 WL 1852001, at *14-15 (E.D.N.Y. June 22, 2009) (applying California law and concluding that a different warning would not have "caused any different medical decisions" where the record showed that the doctors "were aware of Zyprexa's risks related to [plaintiff's injuries]"); *Huntman v. Danek Med., Inc.*, No. 97-2155, 1998 WL 663362, at *5 (S.D. Cal. July 24, 1998) (holding, in the medical device context, that "the adequacy of the warnings is immaterial where the doctor knows of the specific risks," citing *Rosburg*, 181 Cal. App. 3d at 735). Plaintiffs claims against Abbott for strict liability and negligence therefore should be dismissed.

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IV. CONCLUSION

In light of Dr. Rich's unequivocal testimony that he was aware of the alleged risk of which Plaintiffs argue Abbott should have warned—and decided that Humira treatment was medically appropriate nonetheless—Plaintiffs cannot establish that the alleged failure to warn was the proximate cause of their alleged injuries. Accordingly, the Court should grant Abbott's motion for summary judgment of Plaintiffs' strict liability and negligence causes of action against Abbott.

DATED: July 7, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who have consented to electronic service are being served with a copy of the attached **DEFENDANT ABBOTT LABORATORIES' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT** via the CM/ECF system on July 7, 2011, or via overnight delivery (Federal Express) to the non-CM/ECF participants listed below.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

DATED: July 7, 2011

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